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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,052	10/12/2001	Benjamin D. Pless	N02-01	1806

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NEUROPACE, INC.
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EXAMINER

LAYNO, CARL HERNANDZ

ART UNIT PAPER NUMBER

3762

DATE MAILED: 08/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

EC

Office Action Summary

Application No.

09/977,052

Applicant(s)

PLESS ET AL.

Examiner

Carl H. Layno 8/2/03

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6,57 and 64-89 is/are rejected.
- 7) ☒ Claim(s) 2,5,7-56 and 58-63 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the mailing or post office address of each inventor. A mailing or post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing or post office address should include the ZIP Code designation. The mailing or post office address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

Drawings

2. Applicant's formal drawings were received by the Office on March 12, 2002 and have been made of record in the file as Paper No.4. These drawings have been approved by both the Draftsperson and the Examiner.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 64-89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In regard to claim 64, the claim appears to be incomplete. The applicant recites in the preamble of claim 64 that it is developing a “template” and that this is to be used for “identifying neurological activity” in people, however, the structural features recited in the claim language fail to mention any “template” and it is unclear how the structures claimed are suppose to interact to form this “template”. Claims 65-89 are also rejected since they depend from this rejected base claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3, 4, 6, and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Dorfmeister et al ‘868.

The Dorfmeister et al ‘868 patent describes a system for predicting and detecting the onset of a seizure in a patient. See Abstract. Both electroencephalogram (EEG) and electrocorticogram (ECoG) signals are monitored. This patent discloses a number of preferred embodiments including an external system, as shown in Fig.1, and a system involving an implantable device (col.17, lines 48). Fig.7 illustrates images obtained from monitored electrographic signals using implanted needles, each having 8 contacts (col.17, lines 63-65), and displayed on the screen of an external device. This external device is preferably an Intel 486 based personal computer (PC) (col.6, lines 42-43). The system is capable of processing real-time

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electrographic data (col.6, lines 44-47) from the patient and includes the "annotation" of continuously recorded signals (col.6, lines 61-62). See Figs.6A and 7 which show annotated electrograph seizure detection and onset markers. The monitored electrographic signals are processed in the personal computer using FIR filtering techniques and a power spectral density (PSD) is calculated (col.15, lines 23-53). Parameters are calculated from this PSD and may be used as templates for detecting state changes (col.15, lines 55-57).

In regard to claims 2 and 3, the use of the template in helping to detect or predict the onset of a seizure is inherent since that is what this device is intended to do (Abstract, lines 8-9).

In regard to claim 6, Figs.6A shows the annotation of onset events in an ECoG signal.

In regard to claim 57, the implanted needle with 8 electrode contacts (col.17, lines 63-65) would inherently transmit its signals to an external host PC for processing.

Allowable Subject Matter

7. Claims 2, 5, 7-56, and 58-63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claim 64 and its depending claims would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

9. The following is a statement of reasons for the indication of allowable subject matter:

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Independent claim 64 recites features of a system for developing a patient-specific template for identifying neurological activity in a human patient including an external apparatus which is capable of transmitting operational parameters to an implantable device and, in general, communicating bi-directionally with it. The reference of Dorfmeister et al '868, cited *supra*, does not recite a programmable implantable device, nor does it define the implantable device has having the capability of communicating with its externally located host computer bi-directionally. Other prior art references, such as Snell '999 (cited herein), fail to recite the use or creation of a "template" and (for Snell '999) fail to recite the use of electrodes attached to the brain.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Snell '999 patent is cited for its pertinent disclosure of a system including an external programmer in bi-directional communication with a programmable implantable medical device. Unlike applicant's device, that of Snell '999 fails to recite the creation of a "template" in the manner claimed and does not monitor neurological activity in a patient's brain.

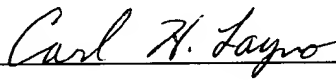
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every

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other Friday between 9AM and 5PM. A voice mail or E-mail message (carl.layno@uspto.gov) may be left if desired.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (703) 308-5181. The current fax number for this Group is (703) 305-3590. Alternatively, for official correspondence, one may use the RightFax number (703) 872-9302 and for unofficial faxes (703) 746-4873. For after final actions, use (703) 872-9303.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Brenda Webb whose telephone number is (703) 305-7520.



CARL LAYNO
PRIMARY EXAMINER

CHL
8/7/03